PATENT

<u>IN THE UNITED STATES PATENT AND TRADEMARK OFFICE</u>

Applicant:	Li Wang	Examiner:	Alyssa M. Alter
Serial No.:	10/684,759	Group Art Unit:	3762
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		Conf. No.:	3360

Title: METHOD AND APPARATUS FOR MONITORING TISSUE FLUID CONTENT FOR USE IN AN IMPLANTABLE CARDIAC DEVICE

Appeal Brief

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following is submitted pursuant to the Notice of Appeal filed January 20, 2011 and responsive to the Notice of Decision dated February 15, 2011.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

I. Real party in interest

The real party in interest in this application is Medtronic, Inc, assignee of the application.

II. Related appeals and interferences

None

III. Status of the claims

80 – 82, 84 – 87 and 96 – 103 are pending. Claims 1 – 79, 83, 88 – 95 and 104 - 107 are cancelled. The rejections of claims 80 – 82, 84 – 87 and 96 – 103 are hereby appealed.

IV. Status of amendments

The Amendment filed November 4, 2010 has been entered. The Appendix of Claims below reflects the claims as finally rejected.

V. Summary of claimed subject matter

The claimed subject matter as set forth in independent claims 80 – 82, 84, 86, 96 – 100 and 102 is discussed below, with support for the various claim limitations in the specification identified.

Claim 80

Claim 80 sets forth a method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

measuring impedance between the two electrodes using the delivered impedance measurement pulse; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and (Steps 435, 440 in Figure 7, discussed in paragraph 109)

wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads. (Steps 620, 625 in Figure 10, discussed in paragraphs 126 – 128)

Claim 81

81. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

measuring impedance between the two electrodes using the delivered impedance measurement pulse; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; (Steps 435, 440 in Figure 7, discussed in paragraph 109)

wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads and declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads. (Steps 620, 625 in Figure 10, discussed in paragraphs 126 – 128)

Claim 82

82. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

measuring impedance between the two electrodes using the delivered impedance measurement pulse; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; (Steps 435, 440 in Figure 7, discussed in paragraph 109)

wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads and wherein assessment of the integrity of the leads comprises comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount. (Steps 620, 625 in Figure 10, discussed in paragraphs 126 – 128)

<u>Claim 84</u>

84. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

measuring impedance between the two electrodes using the delivered impedance measurement pulse; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and (Steps 435, 440 in Figure 7, discussed in paragraph 109)

declaring the set of impedance data flawed is performed responsive to a said measured impedance differing from a prior said measured impedance by more than a defined amount. (Steps 655, 665 and 675 in Figure 12, discussed in paragraphs 132 – 137)

<u>Claim 86</u>

86. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

measuring impedance between the two electrodes using the delivered impedance measurement pulse; (Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data(Part of process of steps 415, 420,425 and 430 in Figure 7, discussed in paragraphs 105 – 107.)

;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and (Steps 435, 440 in Figure 7, discussed in paragraph 109)

wherein the device comprises at least a third electrode and wherein the method further comprises performing a cross check of the measured impedance values by measuring an impedance using the third electrode. (Steps 655, 665 and 675 in Figure 12, discussed in paragraphs 132 – 137) (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

<u>Claim 96</u>

96. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

means for determining occurrences of cardiac events; (Sensing circuitry 200 illustrated in Figure 2 and discussed in paragraphs 46 – 47)

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising: (fluid status monitor 260 in Figure 2, under control of mocroprocessor 224, as described generally in paragraphs 48 – 52 and 57 – 64, and illustrated in more detail in Figure 5 and described in more detail as discussed below)

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom; (excitation pulse control circuitry 314 under control of FSM control 320, as discussed in paragraphs 85 – 87)

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and (Current monitor 350, voltage monitor 312 and microprocessor 224 (Figure 2). As described in paragraphs 89 – 91, the monitored voltage and current are used by the microprocessor 224 to calculate impedance according to Ohm's law)

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and (microprocessor 224, Figure 2, operating according to programming as illustrated in the flow chart of Figure 7 and discussed above in conjunction with the method claims)

wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads. (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40) (the lead integrity is assessed by the microprocessor 224 operating according to programming as illustrated in the flow chart of Figure 11 and discussed above in conjunction with the method claims)

<u>Claim 97</u>

97. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

means for determining occurrences of cardiac events; (Sensing circuitry 200 illustrated in Figure 2 and discussed in paragraphs 46 – 47)

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of

impedance data, the impedance measurement means comprising: (fluid status monitor 260 in Figure 2, under control of microprocessor 224, as described generally in paragraphs 48 – 52 and 57 – 64, and illustrated in more detail in Figure 5 and described in more detail as discussed below)

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom; (excitation pulse control circuitry 314 under control of FSM control 320, as discussed in paragraphs 85 – 87)

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and (Current monitor 350, voltage monitor 312 and microprocessor 224 (Figure 2). As described in paragraphs 89 – 91, the monitored voltage and current are used by the microprocessor 224 to calculate impedance according to Ohm's law)

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and (microprocessor 224, Figure 2, operating according to programming as illustrated in the flow chart of Figure 7 and discussed above in conjunction with the method claims)

wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads; and (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

further comprising means for declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads. (the lead integrity is assessed by the microprocessor 224 operating according to programming as illustrated in the flow chart of Figure 11 and discussed above in conjunction with the method claims)

<u>Claim 98</u>

98. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

means for determining occurrences of cardiac events; (Sensing circuitry 200 illustrated in Figure 2 and discussed in paragraphs 46 – 47)

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising: (fluid status monitor 260 in Figure 2, under control of microprocessor 224, as described generally in paragraphs 48 – 52 and 57 – 64, and illustrated in more detail in Figure 5 and described in more detail as discussed below)

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom; (excitation pulse control circuitry 314 under control of FSM control 320, as discussed in paragraphs 85 – 87)

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and (Current monitor 350, voltage monitor 312 and microprocessor 224 (Figure 2). As described in paragraphs 89 – 91, the monitored voltage and current are used by the microprocessor 224 to calculate impedance according to Ohm's law)

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and (microprocessor 224, Figure 2, operating according to programming as illustrated in the flow chart of Figure 7 and discussed above in conjunction with the method claims)

wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads; and; (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

wherein the means for assessment of the integrity of the leads comprises means for comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount. (the lead integrity is assessed by the microprocessor 224 operating according to programming as illustrated in the flow chart of Figure 11 and discussed above in conjunction with the method claims)

<u>Claim 99</u>

99. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

means for determining occurrences of cardiac events; (Sensing circuitry 200 illustrated in Figure 2 and discussed in paragraphs 46 – 47)

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising: (fluid status monitor 260 in Figure 2, under control of microprocessor 224, as described generally in paragraphs 48 – 52 and 57 – 64, and illustrated in more detail in Figure 5 and described in more detail as discussed below)

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom; (excitation pulse

control circuitry 314 under control of FSM control 320, as discussed in paragraphs 85 – 87)

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and (Current monitor 350, voltage monitor 312 and microprocessor 224 (Figure 2). As described in paragraphs 89 – 91, the monitored voltage and current are used by the microprocessor 224 to calculate impedance according to Ohm's law)

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and (microprocessor 224, Figure 2, operating according to programming as illustrated in the flow chart of Figure 7 and discussed above in conjunction with the method claims)

further comprising means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than a defined amount. (the comparison is done by the microprocessor 224 operating according to programming as illustrated in the flow chart of Figure 12 and discussed above in conjunction with the method claims)

<u>Claim 100</u>

100. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

means for determining occurrences of cardiac events; (Sensing circuitry 200 illustrated in Figure 2 and discussed in paragraphs 46 – 47)

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising: (fluid status monitor 260 in Figure 2, under control of mocroprocessor 224, as described generally in paragraphs 48 – 52 and 57 – 64, and illustrated in more detail in Figure 5 and described in more detail as discussed below)

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom; (excitation pulse control circuitry 314 under control of FSM control 320, as discussed in paragraphs 85 – 87)

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and(Current monitor 350, voltage monitor 312 and microprocessor 224 (Figure 2). As described in paragraphs 89 – 91, the monitored voltage and current are used by the microprocessor 224 to calculate impedance according to Ohm's law)

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and (microprocessor 224, Figure 2, operating according to programming as illustrated in the flow chart of Figure 7 and discussed above in conjunction with the method claims)

further comprising means for declaring the set of impedance data flawed responsive to a measured impedance differing from a prior measured impedance by more than a defined amount. (the comparison is done by the microprocessor 224 operating according to programming as illustrated in the flow chart of Figure 12 and discussed above in conjunction with the method claims)

<u>Claim 102</u>

102. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,: (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

means for determining occurrences of cardiac events; (Sensing circuitry 200 illustrated in Figure 2 and discussed in paragraphs 46 – 47)

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising: (fluid status monitor 260 in Figure 2, under control of mocroprocessor 224, as described generally in paragraphs 48 – 52 and 57 – 64, and illustrated in more detail in Figure 5 and described in more detail as discussed below)

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom; (excitation pulse control circuitry 314 under control of FSM control 320, as discussed in paragraphs 85 – 87)

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and (Current monitor 350, voltage monitor 312 and microprocessor 224 (Figure 2). As described in paragraphs 89 – 91, the monitored voltage and current are used by the microprocessor 224 to calculate impedance according to Ohm's law)

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and further comprising: (microprocessor 224, Figure 2, operating according to programming as illustrated in the flow chart of Figure 7 and discussed above in conjunction with the method claims)

a third electrode; (electrodes 8, 17, 21, 20, 23, 24, 26, and housing 11 illustrated in Figure 1, as described in paragraph 40)

means for measuring an impedance employing the third electrode and (fluid status monitor 260 in Figure 2, under control of mocroprocessor 224, as described generally in paragraphs 48 – 52 and 57 – 64, and illustrated in more detail in Figure 5 and described in more detail as discussed above)

means for performing a cross check of the set of impedance data by measuring an impedance using the third electrode. (the comparison is done by the microprocessor 224 operating according to programming as illustrated in the flow chart of Figure 12 and discussed above in conjunction with the method claims)

VI. Grounds of rejection to be reviewed on appeal

In the Official Action, all remaining claims were rejected as obvious over U.S Patent No. 5,957,861, issued to Combs, et al. in view of Scheulke, et al.(US 5,775,742) This rejection is respectfully traversed for the reasons set forth below. Independent arguments for selected groups of claims are set forth in sections A – E as listed below:

A. The rejections of claims 80 – 82 and 96 - 98

B. Rejections of Claims 86, 87, 102 and 103

C. Rejections of Claims 81 and 97

D. Rejections of Claims 87 and 103

E. Rejections of Claims 84, 85, 86, 99, 100 and 101

VII. Argument

In the Official Action, all remaining claims were rejected as obvious over U.S Patent No. 5,957,861, issued to Combs, et al. in view of Scheulke, et al.(US 5,775,742)

This rejection is respectfully traversed for the reasons set forth below. Independent arguments for selected groups of claims are set forth in sections A – E as listed below:

A. The rejections of claims 80 – 82 and 96 - 98

It perhaps needs to be again emphasized that the limitations of the above claims require that the same set of measurement pulses produce both the fluid measurement and the lead integrity measurement, and that these measurement pulses must be delivered at predetermined intervals following cardiac events. The Examiner's apparent proposed combination of the references is that the impedance measurements as in Scheulke should be taken during delivery of the pacing pulses of Combs.

Applicants have previously noted that the proposed combination still does not produce a device meeting the claims for three reasons, none of which are disputed by the Examiner.

1. Measurement during pacing pulses in Scheulke does not teach measurement using the same mechanism as in Combs.

Even if the measurements of impedance as in Scheulke are done during delivery of the pacing pulses, they are still done using the high voltage circuitry. Addition of the measurement system of Scheulke to Combs still produces a device with two fundamentally different impedance measuring systems, precisely as previously stated by Applicants.

Applicants' previous argument on this point was intended to address the Examiner's contention that combining the two references would produce a device in which fluid content and lead integrity are measured using the same mechanism. Neither reference suggests this conclusion.

2. Measurement during pacing pulses in Scheulke does not even teach measurement at the same time as in Combs.

The measurement of impedances as in Combs does not occur during the pacing pulses. It is done using the pacing pulse circuitry, but not during delivery of the pacing pulses. The impedance measuring drive signal applied to the tissue differs from the pacing pulses and thus cannot be done during delivery of the pacing pulses. If lead impedance measurement is done during the pacing pulses as in Scheulke as now argued by the Examiner, it cannot be incorporated into Combs and have the result of using the same mechanism to both measure lead integrity and fluid content as required by the claims. The teaching in Scheulke now relied upon by the Examiner thus teaches directly away from the claimed invention rather than making it obvious.

3. Measurement during pacing pulses as in Scheulke is irrelevant to the invention as claimed

The claims do not require measurement during the delivery of pacing pulses. The claims require that measurement occurs: (a) responsive to a cardiac event and (b) at a predetermined interval therefrom. Even if delivery of the pacing pulse is understood to be a "cardiac event", delivery during a cardiac event cannot be reasonably understood to be delivery at an interval therefrom. Thus, even if all impedance measurements were taken during the pacing pulses as apparently proposed by the Examiner, the claims would still not be met.

In response to the above arguments, the Advisory Action states as follows:

> Continuation of 11. does NOT place the application in condition for allowance because: the arguments are not found persuasive. The Applicant argues the "assition of the lead integrity measurement system of Scheulke to Combs thus would result in a device having two separate impedance measuring systems. In response to this the Applicant is reminded that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

This is an accurate citation of the law, but the claims require that the same impedance measuring mechanism is used for both lead integrity and fluid content, and

the cited references use substantially different systems for each type. Even if the references were combined, they are inconsistent with one another. In order to make the claimed invention obvious, the Examiner is obligated to explain how and why the references would be modified in conjunction with the proposed combination in order to produce the claimed invention. The Examiner has made no attempt to do so.

Under the specificity requirements in the guidelines for obviousness rejections, it is respectfully asserted that the Examiner is required to specifically explain:

a) where and how the "combined teachings" suggest using the same mechanism to measure both types of impedances; and, in particular

b) what resulting structure the "combined teachings" suggest.

The Final Action and the Advisory Action do not address any of the above arguments or dispute any of the contentions therein. They do not address either item a) or item b) above. As such, the rejection is respectfully asserted to be improper.

Moreover, the Advisory Action, rather than clarifying the grounds for rejection, actually muddies the waters, by specifically stating that the "combined teaching" of the references suggests something that clearly <u>isn't</u> the claimed invention. In particular, the Advisory Action states:

> As a result, the combined teachings of Scheulke and Combs yeild an implanted cardiac stimulation device that monitors intra-thoracic fluid content and lead integrity through impedance data. Therefore the claims stand rejected under Combs in view of Scheulke.

As discussed above, the Examiner's stated result of the "combined teaching" is <u>entirely consistent with Applicant's arguments</u> that the combined teaching suggests a device which measures both lead integrity and fluid content using impedance data <u>obtained though the two separate mechanisms</u> as disclosed in the "combined teaching".

With all due respect, to refute an argument, the Examiner needs to actually and expressly dispute some part of it. As such, the rejection is again respectfully asserted to be improper for this reason as well.

The Examiner's proposed combination is also clearly contrary to the express teaching of the references and does not produce the claimed invention even if implemented as proposed by the Examiner. Under the recently issued guidelines for rejections under Section 103, the rejections are plainly deficient.

B. Rejections of Claims 86, 87, 102 and 103

Applicants previously set forth two reasons these claims were improperly rejected.

1. Cross-checking of measured impedances between two electrodes

Applicants previously stated:

"These claims are rejected based upon the assertion that Scheulke teaches cross-checking of measured impedances between two electrodes by measuring impedance using a third electrode. However, the portions of Scheulke discussed in conjunction with this rejection deal with individual impedance measurements of individual lead impedances performed using three electrodes. A single measurement of each relevant lead impedance is made using a different selected set of three electrodes. The cross checking function as claimed simply is not present. Claims 86, 87, 102 and 103 (as renumbered) are this respectfully asserted to be patentable over the cited references for this reason, regardless of the patentability of the other claims."

The Final Office Action and Advisory do not address, respond to or dispute the above statements as would be required for a proper rejection under the guidelines.

Withdrawal of the rejections of claims 86, 87, 102 and 103 is again respectfully requested for this reason.

2. Set of impedances indicative of tissue fluid content

Applicants also previously stated:

"Further, these claims all require that the impedance measurements which are cross checked are a <u>set of impedances indicative of tissue fluid content</u>. This aspect of the claimed is similarly undisclosed in Scheulke. The impedance measurements of Scheulke are of lead impedance and are not cross-checked as a set for any purpose whatsoever."

The Final Office Action and Advisory do not address, respond to or dispute the above statements as would be required for a proper rejection under the guidelines.

Withdrawal of the rejections of claims 86, 87, 102 and 103 is respectfully requested for this reason as well.

<u>C. Rejections of Claims 81 and 97</u>

Applicants previously set forth two reasons these claims were improperly rejected.

<u>1. Impedances indicative of fluid content valid or invalid as a result of the lead integrity measurement</u>

Applicants previously stated:

"These claims require declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the lead integrity measurement. Neither combs'861 nor Scheulke discloses or suggests this aspect of the claimed invention."

The Final Office Action and Advisory do not address, respond to or dispute the above statements as would be required for a proper rejection under the guidelines.

Withdrawal of the rejections of claims 81 and 97 is again respectfully requested for this reason as well.

<u>2. First Office Action did not even mention this aspect of the claimed invention</u>

Applicants previously stated:

"Further, because the Office Action does not even mention this aspect of the claimed invention it is respectfully asserted that the rejection under Section 103 is inadequate as a matter of law for not clearly setting forth an argument as to why the combination of the cited references makes this aspect of the invention obvious."

The Final Office Action and Advisory do not address, respond to or dispute the above statements as would be required for a proper rejection under the guidelines.

Withdrawal of the rejections of claims 81 and 97 is again respectfully requested for this reason as well.

D. Rejections of Claims 87 and 103

Applicants previously set forth two reasons these claims were improperly rejected.

1. Declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the cross-check measurement

Applicants previously stated:

"These claims require declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the cross-check measurement. Neither combs'861 nor Scheulke discloses or suggests this aspect of the claimed invention. Claims 87and 103 (as renumbered) are this respectfully asserted to be independently patentable over the cited references for this reason, regardless of the patentability of the other claims."

The Final Office Action and Advisory do not address, respond to or dispute the above statements as would be required for a proper rejection under the guidelines.

Withdrawal of the rejections of claims 87 and 103 is again respectfully requested for this reason as well.

2. The First Office Action did not even mention this aspect of the claimed invention

Applicants previously stated:

"Further, because the Office Action does not even mention this aspect of the claimed invention, it is respectfully asserted that the rejection under Section 103 is inadequate as a matter of law for not clearly setting forth an argument as to why the combination of the cited references makes this aspect of the invention obvious."

The Final Office Action does not respond to or dispute the above statement.

Withdrawal of the rejections of claims 87 and 103 is respectfully requested for this reason as well.

E. Rejections of Claims 84, 85, 86, 99, 100 and 101 (as renumbered)

Applicants previously set forth two reasons these claims were improperly rejected.

1. <u>Comparing the set of measured impedances indicative of fluid content to prior measured impedances and declaring the data set valid or invalid as a result of this comparison</u>

Applicants previously stated:

"These claims all require comparing the set of measured impedances indicative of fluid content to prior measured impedances and declaring the data set valid or invalid as a result of this comparison. Neither combs'861 nor Scheulke discloses or suggests this aspect of the claimed invention."

The Final Office Action and Advisory do not address, respond to or dispute the above statements as would be required for a proper rejection under the guidelines.

Withdrawal of the rejections of claims 84, 85, 86, 99, 100 and 101 is again respectfully requested for this reason as well.

<u>2. The First Office Action did not even mention this aspect of the claimed invention</u>

Applicants previously stated:

"Further, because the Office Action does not even mention this aspect of the claimed invention, it is respectfully asserted that the rejection under Section 103 is inadequate as a matter of law for not clearly setting forth an argument as to why the combination of the cited references makes this aspect of the invention obvious."

The Final Office Action and Advisory do not address, respond to or dispute the above statements as would be required for a proper rejection under the guidelines.

Withdrawal of the rejections of claims 84, 85, 86, 99, 100 and 101 is again respectfully requested for this reason as well.

It is respectfully requested that any new ground of rejection be in the form of a non-final rejection, as no claims have been amended in a manner that would allow for a second final rejection based upon new references.

Conclusion

All remaining claims are respectfully asserted to be allowable over the Combs '949 patent in view of the Scheulke patent. Reconsideration of the rejections of the remaining claims is respectfully requested.

If any new grounds of rejection are proposed for substantively un-amended claims, it is respectfully asserted that they should be properly set forth in a non-final office action as required by the rules.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: March 9, 2011

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VIII. Claims Appendix

Claims 1 – 79 (Cancelled)

80. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads.

81. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing;

wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads and declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads.

82. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing;

wherein the device comprises leads carrying the electrodes and wherein the method further comprises employing the measured impedances to assess the integrity of the leads and wherein assessment of the integrity of the leads comprises comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount.

83. (Cancelled)

84. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and

declaring the set of impedance data flawed is performed responsive to a said measured impedance differing from a prior said measured impedance by more than a defined amount.

85. The method of claim 84, further comprising declaring the set of impedance data valid responsive to the said measured impedance differing from the said prior measured impedance by less than the defined amount.

86. A method for monitoring intra-thoracic fluid content using an implanted cardiac stimulation device comprising at least two implanted electrodes, the method comprising:

responsive to occurrence of a cardiac event, delivering an impedance measurement pulse at a predetermined interval therefrom;

measuring impedance between the two electrodes using the delivered impedance measurement pulse;

performing the first three steps repeatedly over a period extending over multiple days to acquire a set of impedance data;

employing the set of impedance data to determine whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises at least a third electrode and wherein the method further comprises performing a cross check of the measured impedance values by measuring an impedance using the third electrode.

87. The method of claim 86, wherein the method further comprises declaring the set of impedance data flawed is performed responsive to the impedance measured using the third electrode.

88 – 95. (Cancelled)

96. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads.

97. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads; and

further comprising means for declaring the set of impedance data flawed responsive to the assessment of the integrity of the leads.

98. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

wherein the device comprises leads carrying the electrodes and wherein the device further comprises means for employing the measured impedances to assess the integrity of the leads; and

wherein the means for assessment of the integrity of the leads comprises means for comparing a measured impedance to a prior measured impedance to determine whether the measured impedance differs from the prior measured impedance by more than a defined amount.

99. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

further comprising means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than a defined amount.

100. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and

further comprising means for declaring the set of impedance data flawed responsive to a measured impedance differing from a prior measured impedance by more than a defined amount.

101. The device of claim 99, further comprising means for declaring the set of impedance data valid responsive to a measured impedance differing from a prior measured impedance by less than the defined amount.

102. An implantable device capable of measuring intra-thoracic fluid content, comprising:

at least two implantable electrodes,:

means for determining occurrences of cardiac events;

an impedance measurement means for measuring impedance between the electrodes repeatedly over a period extending over multiple days to acquire a set of impedance data, the impedance measurement means comprising:

means responsive to occurrence of a cardiac event, for delivering an impedance measurement pulse separated by a predetermined interval therefrom;

means for measuring impedance between the two electrodes using the delivered impedance measurement pulse; and

means responsive to the set of impedance data for determining whether intra-thoracic fluid content is increasing or decreasing; and further comprising:

a third electrode;

means for measuring an impedance employing the third electrode and

means for performing a cross check of the set of impedance data by measuring an impedance using the third electrode.

103. The device of claim 102, further comprising:

means for declaring the set of impedance data flawed responsive to the impedance measured using the third electrode.

104 – 107. (Cancelled)

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.